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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,345

12/31/2003

Timothy W. Vanderveen

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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

04/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,345	Applicant(s) VANDERVEEN ET AL.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on January 15, 2008.
2. In the reply, the applicant amended claims 1, 8 and 10-11. Claims 1-19 are pending in the application.
3. Additionally, the applicant amended claim 10 to obviate the previous 112, 2nd paragraph rejection. The rejection of claims 10-11 based on 112, 2nd paragraph is withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield et al. (US 6,213,972) ("Butterfield") in view Fairchild et al. (US 5,032,112) ("Fairchild") further in view of Doan (US 5,087,245).**

Butterfield discloses a system for determining a fault condition in an infusion system providing a primary infusion 152a and a secondary infusion 152b, the infusion system including an infusion pump 16a capable of infusing fluid from a primary container 22a connected to a primary infusion line 12a and a secondary container 22b

connected to the primary infusion line through a secondary infusion line 12b, the secondary infusion line having a valve 16b to control flow of the secondary fluid in the secondary fluid line. See Fig. 17.

Butterfield further discloses a pressure sensor 34a disposed adjacent the primary infusion line 12a below the connection of the secondary infusion line to the primary infusion line, the pressure sensor in operative arrangement with the primary infusion line to measure pressure within the primary infusion line C26 L62- C27 L6.

Butterfield further discloses a processor 30 responsive to the signals provided by the pressure sensor to establish a baseline pressure value and provide an alert 40 that a fault condition exists. C6 L15-27. The processor can further operate the infusion pump to increase the pressure in the primary infusion line and sample the pressure signals after operating the pump to compare these values with the baseline pressure value to provide an alert. C4 L25-53.

Butterfield further discloses the processor only comparing values that were obtained during a time measurement window. C8 L12-23. The processor can operate in a reverse mode to inject a bolus of fluid into the primary infusion line followed by sampling pressure signals and comparing to threshold values to determine if a fault condition exists. C2 L14-16, C6 L66-C7 L10, C7 L63-C8 L23. An electromechanical actuator 20 squeezes and releases the upstream infusion line to increase the pressure

Although Butterfield discloses the invention as substantially claimed, Butterfield does not directly disclose the primary infusion line having a check valve disposed between the primary container and the connection of the secondary infusion line to the

primary infusion line. Fairchild, in the analogous art, teaches a check valve 42 between the primary container and the connection of the secondary infusion line to the primary infusion line, Fig. 1. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Butterfield with the check valve as taught by Fairchild for preventing the flow backwards from the primary infusion line into the primary container. Regarding claims 10-11, Fairchild further teaches a controllable pressure application device 54 (roller clamp in Fig. 1) for applying pressure to the primary infusion line. This type of manual pressure application device could also be interpreted to be an automatic part of the pump mechanism 16b of the secondary infusion 152b of Butterfield that responds to signals from the processor 30b to apply pressure to the primary infusion line.

Further, Butterfield does not directly disclose a memory for storing pressure related values. Doan, in the analogous art, teaches a memory 26 for storing pressure related values. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Butterfield with the memory as taught by Doan for associating the processor with a memory.

Response to Arguments

6. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that none of the references show or suggest a system for determining status in an infusion system that has a secondary infusion capability. Butterfield, as shown above, is a system that has a secondary infusion capability and discloses a

system for determining infusion status in both the primary and secondary infusion lines by processors 30a, 30b and 30c.

7. Applicant further argues that the references do not show or suggest a method for determining whether a valve in a secondary infusion line is opened during a secondary infusion, or determining the status of a secondary infusion. The valve in the secondary infusion line is part of the pump mechanism 16b and the processor system 30b determines the status of the secondary infusion as the processor 30a determines the status of the primary infusion.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767